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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/597,991

06/21/2007

Eric James Wall

CHM-021M

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HASSE & NESBITT LLC
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SUITE C
CINCINNATI, OH 45249

EXAMINER

PRICE, NATHAN R

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,991	Applicant(s) WALL ET AL.	
	Examiner NATHAN R. PRICE	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/08/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 9 and 20 are objected to because of the following informalities: “wherein the separable base **comprising**” should be corrected as “wherein the separable base **comprises**.” Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar (US 5527287) in view of Woehr et al. (US 20030144627).

4. Regarding claims 1 and 2, Miskinyar discloses a manually-powered injection device for painless inter-muscular injection of an injectable liquid composition from with a reservoir, comprising: a housing 84 (fig. 8-9) having a base for semi-permanent attachment to the skin of a patient (col. 5, ln. 11-14), an injection needle 94 (fig. 8-9) disposed substantially perpendicular to the base and within the housing (see fig. 8), the needle having an injection end (distal end, fig. 8-9), and configured for axial movement manually between a first position (shown in fig. 8) wherein the injection end is within the housing and a second position (shown in fig. 9) wherein the injection end extends outwardly from the base to a distance sufficient for intramuscular insertion thereof (see fig. 9), a means for retaining a reservoir containing an injectable liquid composition (ring

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116 retains reservoir 98 in retracted position prior to use, fig. 8), a means for providing liquid communication between the retained reservoir and the injection needle (proximal end of needle 94 is held in communication with reservoir 98 via its attachment to carriage 96, fig. 8), and a means for injecting the injectable liquid composition from the retained reservoir through the needle, wherein the means for injecting is a manually-powered spring 128 (fig. 8-9) that is configured to exert pressure upon the injectable liquid composition within the retained reservoir, **except** for the injection needle having an outside diameter greater than 0.10 mm and less than about 0.38 mm. However, Woehr et al. teaches injection needles with diameters in this range (see table 1, page 5, which specifically mentions needle outer diameters of .3 mm, .33mm, and .35 mm). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Miskinyar apparatus such that the injection needle has an outside diameter greater than .10mm and less than about .38 mm, as taught by Woehr et al., for the purpose of providing a needle of sufficiently sized diameter to require an appropriate application of strength for use (par. 0079, table 1).

5. Claims 3-8 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar in view of Woehr et al., and further in view of McWethy et al. (US 7004929).

6. Regarding claims 3-8 and 12-17, Miskinyar in view of Woehr et al. discloses the apparatus as claimed, including means for retracting the injection needle (spring 102, fig. 8), whereby the injection end of the needle can be retracted from its second position to a third position wherein the injection end of the needle is within the housing, a needle

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carriage 96 (fig. 8-9) to which the injection needle is affixed, the needle carriage being configured for axial movement between a first position associated with the first position of the injection needle, and a second position associated with the second position of the injection needle, in response to a manual force applied by a person (usage described in col. 5, ln. 9-27), and an implement (button 104, fig. 8-9) for use in applying the manual force to the needle carriage, **except** for a needle insertion securement configured to retain the inserted needle in its second position while injecting the fluid composition, configured to retain the needle carriage in its second position, a retracting means comprising a disengagement means configured to disengage the needle insertion securement from the needle carriage, and a power means configured to bias the needle carriage to a third position that is associated with a third position of the injection needle wherein the injection end of the needle is within the housing. However, McWethy et al. teaches a needle insertion securement (comprising arm 26 and latch 27, fig. 4) configured to retain the inserted needle in its second position while injecting the fluid composition (col. 5, ln. 48-67), configured to retain the needle carriage in its second position, a retracting means comprising a disengagement means 46 (fig. 5) configured to disengage the needle insertion securement from the needle carriage (col. 6, ln. 11-41), and a power means 24 (fig. 4-5) configured to bias the needle carriage to a third position that is associated with a third position of the injection needle wherein the injection end of the needle is within the housing (col. 6, ln. 11-41). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Miskinyar in view of Woehr et al. apparatus such that a needle

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insertion securement is configured to retain the inserted needle in its second position while injecting the fluid composition, configured to retain the needle carriage in its second position, a retracting means comprises a disengagement means configured to disengage the needle insertion securement from the needle carriage, and a power means is configured to bias the needle carriage to a third position that is associated with a third position of the injection needle wherein the injection end of the needle is within the housing, as taught by McWethy et al., for the purpose of maintaining insertion of the needle in the patient (abstract).

7. Claims 9 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar in view of Woehr et al., and further in view of Flaherty (US 6749587).

8. Regarding claims 9 and 20, Miskinyar in view of Woehr et al. discloses the apparatus as claimed, including a base comprising an adhesive for attachment thereof to the skin of a patient (col. 4, ln. 18-23), **except** for a separable base, a base securement means configured for separable securement of the separable base to the housing, and a base separation means configured for separation of the separable base from the housing. However, Flaherty teaches a separable base and base securement means (fig. 9; col. 17, ln. 3-15; abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Miskinyar in view of Woehr et al. apparatus such that it comprises a separable base, a base securement means configured for separable securement of the separable base to the housing, and a base separation means configured for separation of the separable

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base from the housing, as taught by Flaherty, for the purpose of allowing part of the apparatus to be reused (abstract).

9. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar in view of Woehr et al. and McWerthy et al., and further in view of Landau (US 6264629).

10. Regarding claims 18 and 19, Miskinyar in view of Woehr et al. and McWerthy et al. disclose the apparatus as claimed **except** for the carriage and reservoir comprise cooperating threads that engage and retain, a penetrable membrane, and a piercing conduit to penetrate the penetrable membrane. However, Landau teaches for a carriage and reservoir comprising cooperating threads that engage and retain (col. 5, ln. 25-28), a penetrable membrane 82c (fig. 5), and a piercing conduit 80 (fig. 5) to penetrate the penetrable membrane of the reservoir. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Miskinyar in view of Woehr et al. and McWerthy et al. apparatus such that the carriage and reservoir comprise cooperating threads that engage and retain, a penetrable membrane, and a piercing conduit to penetrate the penetrable membrane, as taught by Landau, for the purpose of allowing use of the apparatus with conventional pre-packaged medications.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN R. PRICE whose telephone number is

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(571)270-5421. The examiner can normally be reached on Monday-Thursday, 7:00 a.m. - 4:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. P./
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763